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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	PDC 116(2)
First Inventor or Application Identifier	Solomon S. Steiner
Title	UNIT DOSE CAPSULES AND DRY POWDER INHALER
Express Mail Label No.	EL 381 202 264 US

JC835 U.S. PTO 09/621098 07/21/00

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* 21] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 15]
4. Oath or Declaration [*Total Pages* 3]
   - a. [X] Unexecuted
   - b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
     - i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   - a. [ ] Computer Readable Copy
   - b. [ ] Paper Copy (identical to computer copy)
   - c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [ ] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
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15. [X] Other: Check for $453.00

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*

[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____

Prior application information: *Examiner* _____ *Group / Art Unit:* _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this Express Mail Transmittal Letter for Patent Application and any documents referred to as attached therein are being deposited with the United States Postal Service on this date, July 21, 2000, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, mailing label number EL 381 202 264 US, addressed to BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.

Teresa R. Spratt

Date: July 21, 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Solomon S. Steiner, Robert Feldstein, Per B. Fog, and Trent Poole

Serial No.: Express Mail Label No.: EL 381 202 264 US

Filed: July 21, 2000 Date of Deposit July 21, 2000

For: UNIT DOSE CAPSULES AND DRY POWDER INHALER

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

EXPRESS MAIL TRANSMITTAL LETTER
FOR PATENT APPLICATION AND CERTIFICATE OF MAILING

Sir:

Pursuant to 35 U.S.C. § 21(a) as amended by Public Law 97-247 and 37 C.F.R. § 1.10, Solomon S. Steiner, Robert Feldstein, Per B. Fog, and Trent Poole enclose for filing the attached patent application entitled "UNIT DOSE CAPSULES AND DRY POWDER INHALER", which claims priority to U.S.S.N. 60/145,464 filed July 23, 1999 and U.S.S.N. 60/206,123 filed May 22, 2000. The application includes 1 page of Abstract, 14 pages of specification, 6 pages of claims, 15 sheets of informal drawings, and an unexecuted Declaration. An executed Declaration, Assignment to Pharmaceutical Discovery Corporation and A Verified Statement Claiming Small Entity Status will be submitted shortly. A check in the amount of $453.00 to cover part of the filing fee is enclosed.

The Commissioner is hereby authorized to charge our deposit order account no. 01-2507 in the amount of $753.00 for the remainder of the filing fee, which represents the difference between the filing fee for a large entity and small entity.

This application is being filed on July 21, 2000 by mailing the application to the Assistant Commissioner for Patents, Washington, D.C. 20231 via the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10. The Express Mail label number appears in the heading of this paper, which is attached to the application papers pursuant to 37 C.F.R. § 1.10(b).

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Order Account No. 01-2507. To facilitate this process, applicants have enclosed a duplicate of this letter.

All correspondence concerning this application should be mailed to:

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Respectfully submitted,

Felipe J. Farley
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Date: July 21, 2000

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this Express Mail Transmittal Letter for Patent Application and any documents referred to as attached therein are being deposited with the United States Postal Service on this date, July 21, 2000, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, mailing label number EL 381 202 264 US, addressed to BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.

Teresa R. Spratt

Date: July 21, 2000

APPLICATION

FOR

UNITED STATES LETTERS PATENT

BY

SOLOMON S. STEINER

ROBERT FELDSTEIN

PER B. FOG

AND

TRENT POOLE

FOR

UNIT DOSE CAPSULES AND DRY POWDER INHALER

UNIT DOSE CAPSULES AND DRY POWDER INHALER

FIELD OF THE INVENTION

The present invention is in the field of inhalers.

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority to U.S.S.N. 60/145,464 filed 23 July 1999, entitled Dry Powder Inhaler, and U.S.S.N. 60/206,123 filed 22 May 2000, entitled Unit Dose Capsules and Dry Powder Inhaler Device.

BACKGROUND OF THE INVENTION

In the early 1970's it was found that certain medicines could be administered in dry-powder form directly to the lungs by inhalation through the mouth or inspiration through the nose. This process allows the medicine to bypass the digestive system, and may, in certain cases, allow smaller does to be used to achieve the same results or orally ingested or injected medicines. In some cases, it provides a delivery technique that reduces side effects for medicines taken by other medicines.

Inhaler devices typically deliver their medicinal in a liquid mist or a powder mist. The liquid mist is typically created by a chlorofluorocarbon propellant. However, with the ban on chlorofluorocarbons by the Montreal protocol, interest has turned to dry powder inhalers.

For a dry powder inhaler to work effectively, it must deliver fine particles of medicinal powder that do not agglomerate, and do not end up striking, and being absorbed by the patient's mouth or upper oropharyngeal region. Air flow must therefore not be too fast. Furthermore, it should not be difficult for a patient to load with medicine or to use with the proper technique. Current dry particle inhalers fail in one or more of these important criteria.

SUMMARY OF THE INVENTION

Described is a dry powder inhaler comprising an intake section; a mixing section, and a mouthpiece. The mouthpiece is connected by a swivel joint to the mixing section, and may swivel back onto the intake section and be enclosed by a cover. The intake chamber comprises a special piston with a tapered piston rod and spring, and one or more bleed-through orifices to modulate the flow of air through the device. The intake chamber further optionally comprises a feedback module to generate a tone indicating to the user when the proper rate of airflow has been achieved. The mixing section holds a capsule with holes containing a dry powder medicament, and the cover only can open when the mouthpiece is at a certain angle to the intake section. The mixing section further opens and closes the capsule when the intake section is at a certain angle to the mouthpiece. The mixing section is a Venturi chamber configured by protrusions or spirals to impart a cyclonic flow to air passing through the mixing chamber. The mouthpiece includes a tongue depressor, and a protrusion to contact the lips of the user to tell the user that the DPI is in the correct position. An optional storage section, with a cover, holds additional capsules. The cover for the mouthpiece, and the cover for the storage section may both be transparent magnifying lenses.

The capsules may be two-part capsules where each portion has apertures which correspond to apertures in the other half when each half is partially fitted to the other half, and fully fitted to the other half. All the apertures may be closed when the two halves are rotated around their longitudinal axes with respect to each other. Each capsule may have a unique key on each half that only fits with a particular inhaler.

Therefore it is an object of the invention to provide a dry particle inhaler that can fold into a compact form.

Therefore it is an object of the invention to provide a dry particle inhaler that can be loaded with medicament easily.

Therefore it is an object of the invention to provide a dry particle inhaler where the small writing on a capsule of medicament can be easily read.

Therefore it is an object of the invention to provide a dry particle inhaler where a capsule containing medicament can only be inserted when a person unfolds the inhaler for use.

Therefore it is an object of the invention to provide a dry particle inhaler where the air flow through the device is regulated.

Therefore it is an object of the invention to provide a dry particle inhaler to provide a means for indicating to the user when the air flow is at the correct rate.

Therefore it is an object of the invention to provide a dry particle inhaler where particles of drug are dispersed finely.

These and other objects of the invention will be readily apparent upon a reading of the present specification, claims and drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Figure 1 is a schematic view of the dry particle inhaler described herein.

Figure 2 is schematic view of the mouthpiece cover.

Figure 3 is schematic view showing the angle between the intake section and the mouthpiece.

Figure 4 is a schematic view of the dry particle inhaler, showing the storage section.

Figure 5 is a schematic view of the intake section of the dry particle inhaler, showing the flow regulator and the feedback module.

Figure 6 is a schematic view of the mixing section.

Figure 7 is a schematic view of a capsule to hold medicament.

Figure 8 is a schematic view of the mouthpiece.

Figure 9 is a perspective view of a specific embodiment of the dry particle inhaler in the closed position, with a capsule inserted into the mixing section, and extra capsules stored in the storage section.

Figure 10 is a perspective view of a specific embodiment of the dry particle inhaler showing a capsule being loaded in to the mixing section.

Figure 11 is a perspective view of a specific embodiment of the dry particle inhaler showing a capsule inserted into the mixing section, and the mouthpiece extended for use.

Figures 12, 13, 14, and 15 follow each other in temporal sequence.

Figure 12 is a perspective view of a specific embodiment of the dry particle inhaler showing a closed mouthpiece cover.

Figure 13 is a perspective view of a specific embodiment of the dry particle inhaler showing an open mouthpiece cover.

Figure 14 is a perspective view of a specific embodiment of the dry particle inhaler showing an open mouthpiece cover, an open mixing section cover, and a capsule about to be inserted into the mixing section.

Figure 15 is a perspective view of a specific embodiment of the dry particle inhaler showing the mouthpiece extended for use.

Figure 16 is a view of a pneumatic circuit, where air flows (fluid flows) are represented by their electrical equivalents.

Figure 17 is a schematic view of the dry particle inhaler.

Figure 18 is a cutaway view of a capsule and a portion of the mixing section.

Figure 19 is a cutaway view of half of a capsule, showing a cone in the interior and a secondary hole with a chamfered, or beveled, edge.

TABLE OF REFERENCE NUMBERS

10	dry powder inhaler device
20	intake section
30	mixing section
40	mouthpiece
50	air passage through dry powder inhaler device
60	longitudinal axis of intake section
70	longitudinal axis of mouthpiece section

80 swivel joint connecting mouthpiece and mixing section

90 cover for mouthpiece

100 protrusions on mouthpiece cover

110 depressions on dry particle inhaler cover to mate with protrusions on mouthpiece cover

120 tongue depressor on mouthpiece

130 protrusion on surface of mouthpiece to contact lips of device user

135 opening of mouthpiece to be fitted into user's mouth

140 intake port

150 flow regulator

160 bleed orifice

170 piston

180 piston head

190 piston rod

200 proximal portion of piston rod

210 distal portion of piston rod

220 spring

230 inner walls of intake section inner chamber

240 feedback module

250 mechanical fasteners in storage section

260 holder in mixing section for capsule

270 Venturi chamber

280 spiral shape or protrusions to impart cyclonic flow to air

290 cover for mixing chamber

291 interior of mixing section

292 air flow entrance to mixing section

294 air flow exit from mixing section

296 latch mechanism for mixing section cover

298 interior wall of mixing section

300 capsule

310 first tube

320 open end of first tube

330 closed end of first tube

340 long axis of first tube

350 protrusion on first tube

360 keying surface on first tube

370 secondary holes in first tube

372 chamfered edge of secondary hole

375 cone in interior of first tube

380 second tube

390 open end of second tube

400 closed end of second tube

410 long axis of second tube

420 protrusion on second tube

430 keying surface on second tube

440 secondary holes in second tube

445 cone in interior of second tube

450 hand of user

460 air flow direction

470 storage section

480 storage section cover

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 is a schematic drawing of the dry powder inhaler (10) described herein. It comprises an intake section (20), a mixing section (30) and a mouthpiece (40). An air passage (50) goes through the intake section (20), a mixing section (30) and a mouthpiece (40). A swivel joint (80) connects the mouthpiece (40) to the mixing section (30). The mixing section (20) has a cover (290) which may be a transparent magnifying lens. Arrow (460) shows the direction of air flow through the air passage (50) through the dry powder inhaler (10).

Figure 2 shows the mouthpiece cover (90) in the closed position over the dry particle inhaler (10). Protrusions (100) on the mouthpiece cover (90) mate with grooves or depressions (110) on the dry particle inhaler (10), to join the mouthpiece cover (90) to the dry particle inhaler (10).

Figure 3 is a schematic of the showing the mouthpiece (40) and the intake section (20) as represented by the longitudinal axis of the mouthpiece (70) and the longitudinal axis of the intake section (60). The swivel joint (80) connecting the mouthpiece (40) to the intake section (20) at the mixing section (30) may be regarded as the vertex of the angle. The importance of the angle (here called theta) between these two longitudinal axes will be further explained.

Figure 4 shows the dry particle inhaler (10) with a storage section (470). Indicated as being inside the storage section (470) are mechanical fasteners (250) which operate to hold medicament capsules (300) (not shown in this Figure) in the storage section. In this embodiment, the storage section (470) is shown as appended to the intake section (20). The storage section has a cover (480) which may be a transparent magnifying lens, to allow the user to easily read writing on medicament capsules stored therein. The storage section cover (480) may swivel outward, or slide open on a track (not shown), or open by a variety of mechanisms known to those of skill in the art.

Figure 5 shows the intake section (20) of the dry particle inhaler (10). The direction of air flow is shown by the arrow (460). Air is admitted through an intake port (140) and one or more bleed orifices (160) [The bleed orifices may also be styled as secondary ambient air intake ports]. The piston (170) normally covers the intake port (140). When the user (not shown) inspires, the piston head (180) is drawn backwards, at a steady rate modulated by the spring (220). The spring (220) is fixed to the piston (170) and the inner wall (230) of the intake section chamber. Thus the rate of air flow is controlled. The air flow is further controlled by the tapering of the piston rod (190), past which the air flows. For further control of the air flow, a second spring (not shown) may also control the rate of movement of the piston (170).

The piston (170) and spring (220) combination allow the user (not shown) to generate a vacuum in his lungs before the intake port (140) opens. Thus, by the time enough vacuum is generated to open the intake port (140), there will be sufficient air flow at a sufficient rate in the dry particle inhaler (10) to draw most of the medicament in the capsule (not shown) out of the inhaler into the proper place in the lungs of the user.

A feedback module (240) generates a signal to the user (not shown), which tells the user whether he is inspiring at the correct rate. The signal may be an audible one, in one embodiment a tone that is at a steady pitch when air flow is at a certain steady rate. In one embodiment of the dry particle inhaler (10), the signal is generated mechanically, such as be a musical reed. In another embodiment of the invention, the signal might be generated electronically, after electronic measurement of the air flow rate. The feedback module (240) would include a means for increasing or lessening the signal strength, or turning the signal off entirely. If the signal were generated by a reed, the mechanism for turning off the signal might be covering a bleed orifice which might admit the air flow generating the signal. If the signal were generated electronically, a simple push button or dial might turn on and off the signal.

Figure 6 shows a schematic of the mixing section (30) of the present invention. The mixing section has a cover (290), and a holder (260) for a medicament capsule (not shown). The holder (260) is a mechanism which grips and turns the capsule (not shown) to open and close it as the longitudinal axis (70) of the mouthpiece is rotated about the swivel joint (80) relative to the longitudinal axis (60)of the intake section. Such a mechanism may be straightforward: in a simplest embodiment, both the top and bottom halves (not shown) of the capsule could be fixed to their respective holders (260).

The Venturi chamber (270) speeds the flow of air near the capsule (not shown). Air flows in at (292), and out through (294). In one embodiment, air flows both through and around a capsule (not shown) holding a dry powder medicament. The special shape of the Venturi chamber (270),

which further includes protrusions or spiral shapes (280), imparts a cyclonic flow to the air passing through the mixing section (30). This helps to de-agglomerate particles of dry powder. The spiral shape of the interior of the mixing section (291) can be two separate spirals, in one embodiment of the invention. Mixing section (30) therefore provides the means whereby air flow is speeded up to suspend dry particles in air and de-agglomerate them, and then slow the air flow somewhat while the particles are still suspended in air. The cover (290) for the mixing section (30) may be a transparent magnifying lens, so that any writing on the capsule (not shown) may be read easily.

In one embodiment of the dry particle inhaler (10), the cover (290) of the mixing section may not be opened unless the longitudinal axis (70) of the mouthpiece forms a certain angle with the longitudinal axis (60) of the intake section, with the vertex of the angle being the swivel joint (80) connecting the mouthpiece (40) and the mixing section (30). The latch mechanism (296) for the cover (290) of the mixing section can accomplish this, by any of several mechanical means known to those of ordinary skill in the art. In the simplest embodiment, a catchment (not shown) in the cover (290) for the mixing chamber would be engaged by a slip ring (not shown) on the mixing section which was only a certain number of degrees of a circle. When the mouthpiece (40) were rotated enough relative to the intake section (20), the slip ring (not shown) would no longer engage the catchment (not shown). In one embodiment, the user could open the cover (290) when the angle were between approximately ninety and one-hundred and eighty degrees.

Figure 7 shows a medicament capsule (300) for use with an inhaler, be it a dry powder inhaler (10), or a liquid mist inhaler. The capsule (300) has two halves which fit together, here styled a first tube (310) and a second tube (380). Each tube has an open end (320, 390), and a closed end (330, 400). Each tube also has a long axis (340, 410). In addition, each tube has a number of secondary holes (370, 440). The first tube (310) fits inside the second tube (380) snugly. A protrusion (350) on the outer surface of the first

tube (310) can slide past a corresponding protrusion (420) on the inner surface of the second tube (380). This locks the first tube (310) to the second tube (380). Therefore the first tube (310) and the second tube (380) have both an unlocked and a locked position. In the unlocked position, at least one secondary hole (370) in the first tube aligns with at least one secondary hole (440) in the second tube. This permits introduction of a medicament (not shown) into the capsule through the aligned secondary holes (370, 440). The first tube (310) may then be locked to the second tube (380). When a user (not shown) is ready to use a capsule (300), he simply places it in the holder (260) in the mixing section (30), and closes the cover (290). When the holder (260) rotates the first tube (310) around its long axis (340) relative to the second tube (380) and its long axis (410) (the axes are now coincident), that causes at least two secondary holes (370) in the first tube to align with at least two secondary holes (440) in the second tube. Air can now pass in, through, and out of the capsule (300), releasing the medicament contained therein. In one embodiment of the inhaler, the capsule (300) might open when the angle between the longitudinal axis (70) of the mouthpiece section, the vertex of the swivel joint (80), and the longitudinal axis (70) of the mouthpiece section were between one hundred and seventy and one-hundred and eighty degrees. This rotation of the mouthpiece (40) relative to the intake section (20) would cause a corresponding rotation of the first tube (310) about its long axis (340) relative to the second tube (380) and its long axis (410).

In one embodiment of the invention, several protrusions on the surfaces of the first tube or the second tube might provide a variety of locking positions. Similarly, a variety of secondary holes in the first and second tubes might provide a variety of rotational positions aligning or not aligning secondary holes on the first and second tubes.

The capsules described herein permit the introduction of liquid or gel medicament which can be dried in the capsule, creating a powder. This permits the accurate production of very small amounts of powdered medicament in a

capsule, since it can be formed from a larger volume of accurately metered liquid or gel medicament. This permits very accurate microdosing. In addition, chemical reactions and drug mixtures may be made directly in the capsules described herein, then the resulting formulation dried.

In one embodiment of the capsule (300), one or more of the secondary holes (370, 440) used to admit air to the capsule is oval-shaped (elliptical). In one embodiment of the invention, the ratio of the long axis of the ellipse to the shorter axis may be between 1:1 and 3:1, and may be 2:1. This ratio may be called a vertical aspect ratio. In one embodiment of the invention, the intersection of the surface defining one or more of the secondary holes (370, 440) and the surface defining the interior of the capsule (300) meet in a chamfered, or beveled, edge. This chamfered edge creates a vortex when air flows through the secondary holes (370, 440).

Each capsule (300) also has a keying surface (or fastening mechanism) on the closed end (330) of the first tube and the closed end (400) of the second tube comprising the capsule. The keying surface (360) on the first tube may be different from the keying surface (430) on the second tube. That permits easy tactile and visual identification of the orientation of the capsule. It also permits a system where each drug formulation in a capsule (300) corresponds to a dry particle inhaler (10), so users cannot mix up drugs. In one embodiment of the invention, the keying surface (360) of the first tube mates with a keying surface (430) of a different second tube, or the mechanical fasteners (250) of the storage section (470). This permits easy storage of the capsules (300) in the storage section (470).

Figure 18 shows a medicament capsule (300), with a keying surface (360) on the first tube and a keying surface (430) on the second tube. It also shows a cutaway view of the mixing section (30) and the air flow entrance (292) to the mixing section and the air flow exit (294) to the mixing section. A spiral shape (280) is given to the interior walls (298) of the mixing section, to impart a cyclonic flow to air passing through. The air flow entrance (292) and air flow

exit (294) in this embodiment are tangential to the imaginary tube we might call the mixing section interior (291). That is to say, if a radius were drawn perpendicular to the long axis of the tube, and a tangent line were drawn to the circle perpendicular to the radius, the air flow would exit the mixing section along that tangent line. The tangential air flow exit (294) increases the velocity of the air flow, and thus helps disperse the medicament particles. As can be seen from Figure 18, the mixing section interior (291) is sized to accommodate a medicament capsule (300). Keying mechanisms (360, 430) are shaped to mate with holder (260) in the mixing section. Capsules according to the present invention may have a number of shapes, including ovoid and rectangular shapes. A variety of shapes of protrusions and slots may also be employed as keying surfaces. For instance, a keying surface might be a rectangular block, and a capsule holder might have a rectangular orifice. Alternatively, a keying surface might be triangular, hexagonal, Z-shaped, C-shaped, etc., and the holder would have the correspondingly shaped aperture.

Figure 18 also shows one embodiment of the capsule (300) where a cone (375) is located in the interior of the first tube, and a cone (445) is located in the interior of the second tube. These cones (375, 445) cause the air flow within the capsule to be cyclonic, aiding in mixing the medicament particles with the air. A cone is shown herein, but other cyclone-creating structures are contemplated by the present invention.

Figure 8 shows the mouthpiece (40) of the dry particle inhaler (10). It has a protrusion (130) on its surface to contact the lips of a user (not shown). This helps the user place the mouthpiece correctly in his mouth. The mouthpiece (40) also includes a tongue depressor (120), which may have a bulbous shape. The mouthpiece (40) is long enough that it fits approximately midway into the user's mouth (not shown). This permits greater delivery of medicament to the lungs, and less delivery to the oral cavity. The mouthpiece (40) has a particular aspect ratio of its inner channel (50) (see Figure 17). This slows the air passing through the channel so that the air borne particulates do not

end up striking the back of the user's throat. However, the air is not slowed so much that the particulates settle out of the air flow.

Figure 9, Figure 10, and Figure 11 show one specific embodiment of the dry particle inhaler (10). In Figure 9, the cover (90) of the mouthpiece is closed, and several capsule (300) are in the storage section (470). In Figure 10, the mouthpiece (40) has been rotated relative to the intake section (20). The longitudinal axis (60) [not shown] of the intake section here makes an approximately ninety degree angle with the longitudinal axis (70) of the mouthpiece section. This permits the cover (290) for the mixing section to be opened. A medicament capsule (300) taken from the storage section (470) is about to be inserted into the mixing section (30). In Figure 11, the mouthpiece (40) has been rotated to a fully extended position, the cover (290) for the mixing section has been closed, and the dry particle inhaler 910) is ready for use. In one embodiment of the dry particle inhaler (10), when the dry particle inhaler is in the closed position (Figure 9), the interior of the intake section (20) would be isolated from the outside air, but the mouthpiece (40) interior and the mixing section interior (291) would not be, permitting them to dry out after being exposed to the humid breath of a user.

Figure 12, Figure 13, Figure 14, and Figure 15 show a temporal sequence where a capsule (300) of medicament is loaded into the mixing section (30) of a dry particle inhaler (10), and the mouthpiece (40) is extended for use. The dry particle inhaler (10) described herein can also be used for nasal delivery of medicaments. A small tube (not shown) can be fitted to the end of the mouthpiece (40), and the other end of the tube inserted into the nostril. Alternatively, the mouthpiece (40) may be replaced by a nosepiece (not shown), whose free end is sized to be inserted into a nostril of a user. In another embodiment, a device such as a bellows or a syringe is used to force air through the dry particle inhaler (10) into a nosepiece inserted into the nostril of a user (not shown).

Figure 16 shows the fluid (air) flow of the dry particle inhaler (10) modeled as the equivalent electrical circuit. This is styled a "pneumatic resistance circuit".

Figure 17 shows a schematic view of the dry particle inhaler (10). The air passage (50) through the dry particle inhaler widens as it goes through the mouthpiece (40) along the direction of the air flow (460). The opening (135) of the mouthpiece to be inserted into the mouth of the user may be roughly ellipsoid, or oval, and thus have a major axis and a minor axis. The ratio of these two may be called the horizontal aspect ratio. In one embodiment of the invention, the horizontal aspect ratio is between 2:1 and 4:1. In one embodiment of the dry particle inhaler (10), the horizontal aspect ratio is 3:1. Shaping the opening (135) in this manner keeps the drug particles collimated, maintains the optimal velocity of the particles in the air stream, and is oriented to the natural horizontal aspect ratio of the oropharyngeal region of the mouth. In one embodiment of the invention, the outline of the opening (135) resembles a bean.

The dry particle inhaler described herein may be used with medicament particles of low, medium, and high shear forces.

The dry particle inhaler and capsules described herein may be made with a variety of suitable materials known to those skilled in the art, such as metal, glass, rubber, and plastic.

While the invention has been described with reference to particular embodiments, those skilled in the art will be able to make various modifications without departing from the spirit and scope thereof.

We claim:

1. A dry powder inhaler comprising:

(a) a intake section; mechanically connected to

(b) a mixing section; mechanically connected to

(c) a mouthpiece;

wherein the intake section, and mouthpiece each have a longitudinal axis; and wherein air flows through a passage extending from the intake section through the mixing section through the mouthpiece; and wherein the mechanical connection between the mouthpiece and the mixing section comprises a swivel joint which allows the longitudinal axis of the intake section to be parallel to the longitudinal axis of the mouthpiece.

2. The dry powder inhaler of claim 1 further comprising a cover mechanically connected to the dry powder inhaler, wherein the cover shelters the mouthpiece.

3. The dry powder inhaler of claim 1 further comprising a cover mechanically connected to the dry powder inhaler, wherein the cover shelters the mixing section.

4. The dry powder inhaler of claim 4 wherein the mixing section cover only opens when the angle defined by the longitudinal axis of the intake section and the longitudinal axis of the mouthpiece and the swivel joint vertex is a fixed number of degrees.

5. The dry powder inhaler of claim 1, wherein the fixed number of degrees the angle must be for the cover to be opened is between approximately ninety degrees and one hundred and eighty degrees.

6. The dry powder inhaler of claim 3 wherein the mixing section cover is translucent and is a magnifying lens.

7. The dry powder inhaler of claim 1 further comprising a storage section mechanically connected to the dry powder inhaler, wherein a cover mechanically connected to the storage section shelters the storage section, and the cover may assume one or more fixed open positions.

8. The dry powder inhaler of claim 7 wherein the storage section cover is translucent and is a magnifying lens.

9. The dry powder inhaler of claim 7 wherein the storage section further includes mechanical fasteners mechanically connected to the storage section to secure capsules within the storage section.

10. The dry powder inhaler of claim 2 wherein the mouthpiece cover is mechanically connected to the dry powder inhaler by means of protrusions on the mouthpiece cover, and wherein the dry powder inhaler further includes corresponding depressions that mate with said protrusions.

11. The dry powder inhaler of claim 1 wherein the intake section includes an inner channel and comprises:

(a) an intake port; covered by

(b) a flow regulator; and

(c) a bleed orifice;

wherein the intake port and the bleed orifice both admit air to the dry powder inhaler, the rate of admission of said air being controlled by both the flow regulator and the bleed orifice and wherein the flow regulator comprises:

(alpha) a piston comprising a piston head connected to a piston rod; and

(beta) one or more springs connected to the piston and the inner walls of the intake chamber; wherein the piston rod wider at the proximal portion connected to the piston head and narrower at the distal portion; and wherein the piston head covers the intake port; and wherein the piston head moves away from the intake port to admit air to the intake port, and wherein movement of the piston head is modulated by the springs connecting the piston to the inner walls of the intake chamber.

12. The dry powder inhaler of claim 11 wherein the intake chamber further includes a feedback module mechanically connected to the intake chamber, wherein the feedback module generates a signal in response to the flow of air in the intake chamber.

13. The dry powder inhaler of claim 12, wherein the feedback module comprises signal generators selected from the group consisting of electronic apparatuses to generate audio signals and mechanical devices to generate audio signals.

14. The dry powder inhaler of claim 12 wherein the strength of the signal from the feedback module may be varied by a user of the dry powder inhaler.

15. The dry powder inhaler of claim 1, wherein the mixing section is a chamber which comprises a holder for a capsule having top and bottom keying portions; and the holder is nested inside the chamber; wherein the holder mechanically grips the top and bottom keying portions of the capsule, and wherein the holder opens the capsule when the angle defined by the longitudinal axis of the intake section and the longitudinal axis of the mouthpiece and the swivel joint vertex is a fixed number of degrees, and closes the capsule when the angle defined by the longitudinal axis of the intake section and the longitudinal axis of the mouthpiece and the swivel joint vertex is a fixed number of degrees.

16. The dry powder inhaler of claim 1, wherein the fixed number of degrees needed to open the capsule is between approximately ninety degrees and one hundred and eighty degrees, and the fixed number of degrees to close the capsule is between approximately ninety and zero degrees.

17. The dry powder inhaler of claim 1, wherein the mixing section is a chamber which comprises a holder for a capsule having top and bottom keying portions; and the holder is nested inside the chamber; wherein the holder mechanically grips the top and bottom keying portions of the capsule, and the holder only admits one capsule with one type of keying portion.

18. The dry powder inhaler of claim 1, wherein the mixing chamber comprises a Venturi chamber that is shaped to give air passing through it a cyclonic flow.

19. The dry powder inhaler of claim 1, wherein the Venturi chamber is shaped so as to keep the air velocity below the inflection speed limit.

20. A dry powder inhaler comprising a mouthpiece sized to extend mid-way into the oral cavity of a user.

21. The dry powder inhaler of claim 20 wherein the mouthpiece further includes a tongue depressor.

22. The dry powder inhaler of claim 21 wherein the tongue depressor has a bulbous shape.

23. The dry powder inhaler of claim 1 wherein the mouthpiece has an outer surface further includes a protrusion on that outer surface to contact the lips of the user and so to indicate to the user that the dry powder inhaler has been inserted into the oral cavity of the user in the correct position.

24. The dry powder inhaler of claim 1 wherein the mouthpiece has an inner channel shaped to keep air flowing at the proper velocity of approach.

25. The dry powder inhaler of claim 2 wherein air is admitted to dry the mouthpiece when the cover is closed.

26. The dry powder inhaler of claim 1 wherein the mouthpiece opening has an approximately 3:1 horizontal aspect ratio.

27. The dry powder inhaler of claim 1 wherein the inhaler was designed using a pneumatic resistance circuit.

28. A capsule for holding a medicament comprising a first tube and a second tube, wherein:

(a) a first tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis; and wherein the first tube has at least one protrusion on its outer surface; and

(b) a second tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis and wherein the second tube has at least one protrusion on its inner surface; and wherein the outer circumference of the first tube is approximately equal to

the inner circumference of the second tube, such that the open end of the first tube can slide snugly into the open end of the second tube; and wherein a protrusion on the outer surface of the first tube may slide past a protrusion on the inner surface of the second tube, locking the tubes together;

and wherein the first tube and the second tube each have one or more secondary holes other than the openings at the end of each tube, wherein at least one secondary hole in the first tube may be made coincident with at least one secondary hole in the second tube when the first tube is slid onto the second tube in the unlocked position by rotation of the first and second tubes about their long axes, and

wherein when the first tube is locked onto the second tube at least two secondary holes in the first tube may be made coincident with at least two secondary holes in the second tube by rotation of the first and second tubes about their long axes.

29. The capsule of claim 28 wherein the first and second tubes further comprise keying surfaces at the closed ends of the tubes.

30. The capsule of claim 28 further including medicament selected from the group consisting of liquid, powder, and gaseous medicaments.

31. A medicament capsule comprising a fastening mechanism to attach it to a second medicament capsule.

32. The medicament capsule of claim 31 wherein the fastening mechanism can attach the capsule to a storage compartment for capsules in an inhaler.

33. A medicament capsule for an inhaler wherein the medicament capsule comprises apertures in the capsule to admit air flow and wherein structures in the interior surface of the capsule create cyclonic air flow.

34. The capsule of claim 33 wherein the structures are cone-shaped.

35. A medicament capsule for a dry particle inhaler having a hole to admit air flow to release medicament into the airstream of the dry particle inhaler wherein the vertical slot ratio of the hole is between 1:1 and 3:1.

36. The medicament capsule of claim 35, wherein the vertical slot ratio is 2:1.

37. A method of making a capsule comprising a powdered medicament comprising the steps of:

(a) introducing a liquid or gel containing medicament into the capsule of claim 28; and

(b) drying the medicament to form a powder.

38. A method of making a capsule comprising a medicament comprising the step of introducing one or more chemicals into the capsule of claim 28.

39. The dry particle inhaler of claim 1, wherein the inner channel of the intake section may be isolated from outside air while the inner channel of the mixing section and the mouthpiece is exposed to outside air.

40. The dry particle inhaler of claim 1, wherein the mixing section has a long axis, and wherein the air flowing through the mixing section to the mouthpiece exits the mixing section at a tangent to a circle described by a radius about the long axis of the mixing section.

UNIT DOSE CAPSULES AND DRY POWDER INHALER

ABSTRACT OF THE DISCLOSURE

Described is a dry powder inhaler comprising an intake section; a mixing section, and a mouthpiece. The mouthpiece is connected by a swivel joint to the mixing section, and may swivel back onto the intake section and be enclosed by a cover. The intake chamber comprises a special piston with a tapered piston rod and spring, and one or more bleed-through orifices to modulate the flow of air through the device. The intake chamber further optionally comprises a feedback module to generate a tone indicating to the user when the proper rate of airflow has been achieved. The mixing section holds a capsule with holes containing a dry powder medicament, and the cover only can open when the mouthpiece is at a certain angle to the intake section. The mixing section further opens and closes the capsule when the intake section is at a certain angle to the mouthpiece. The mixing section is a Venturi chamber configured by protrusions or spirals to impart a cyclonic flow to air passing through the mixing chamber. The mouthpiece includes a tongue depressor, and a protrusion to contact the lips of the user to tell the user that the DPI is in the correct position. An optional storage section, with a cover, holds additional capsules. The cover for the mouthpiece, and the cover for the storage section may both be transparent, magnifying lenses.

The capsules may be two-part capsules where each portion has apertures which correspond to apertures in the other half when each half is partially fitted to the other half, and fully fitted to the other half. All the apertures may be closed when the two halves are rotated around their longitudinal axes with respect to each other. Each capsule may have a unique key on each half that only fits with a particular inhaler.

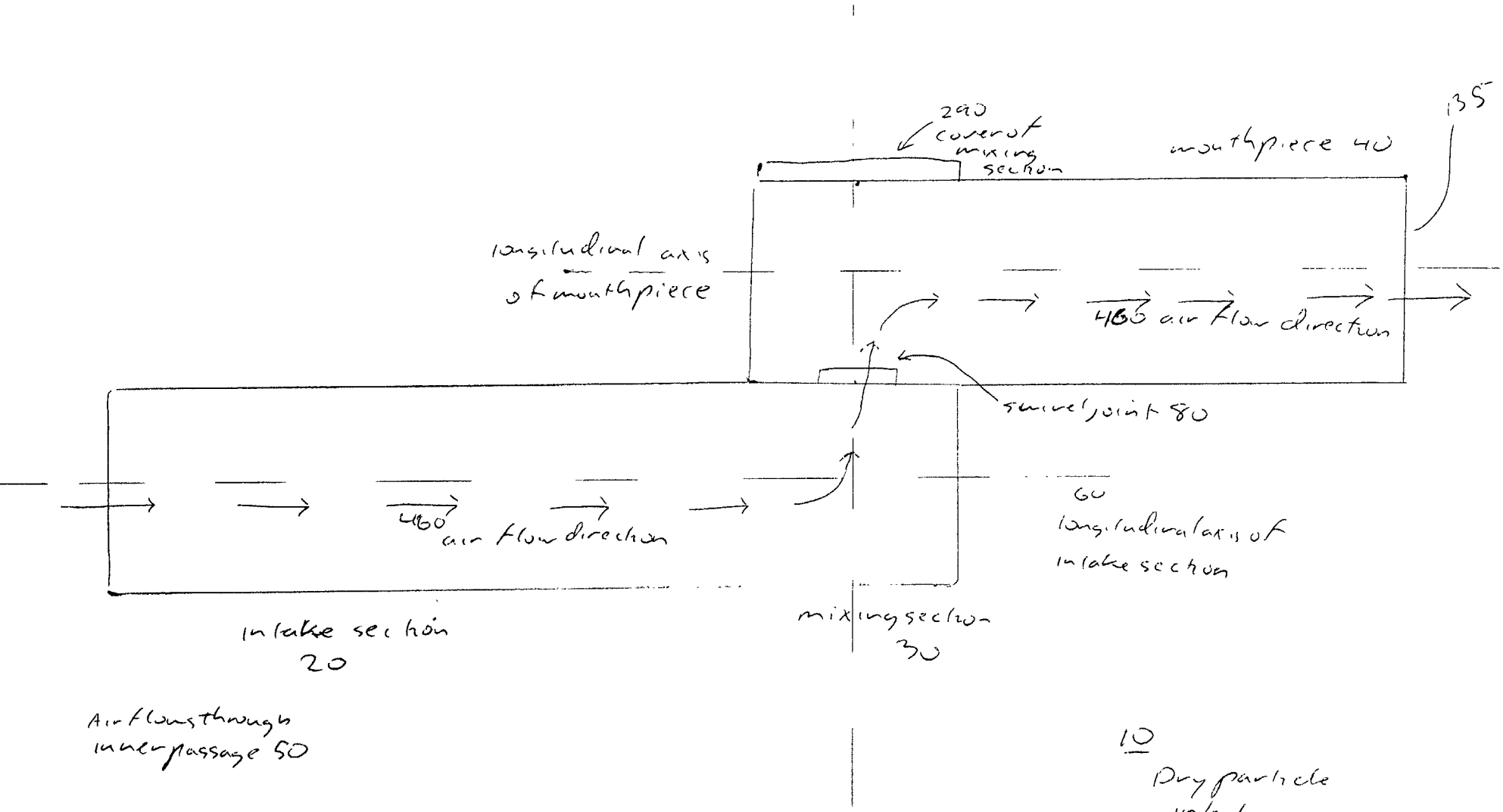


Figure 1

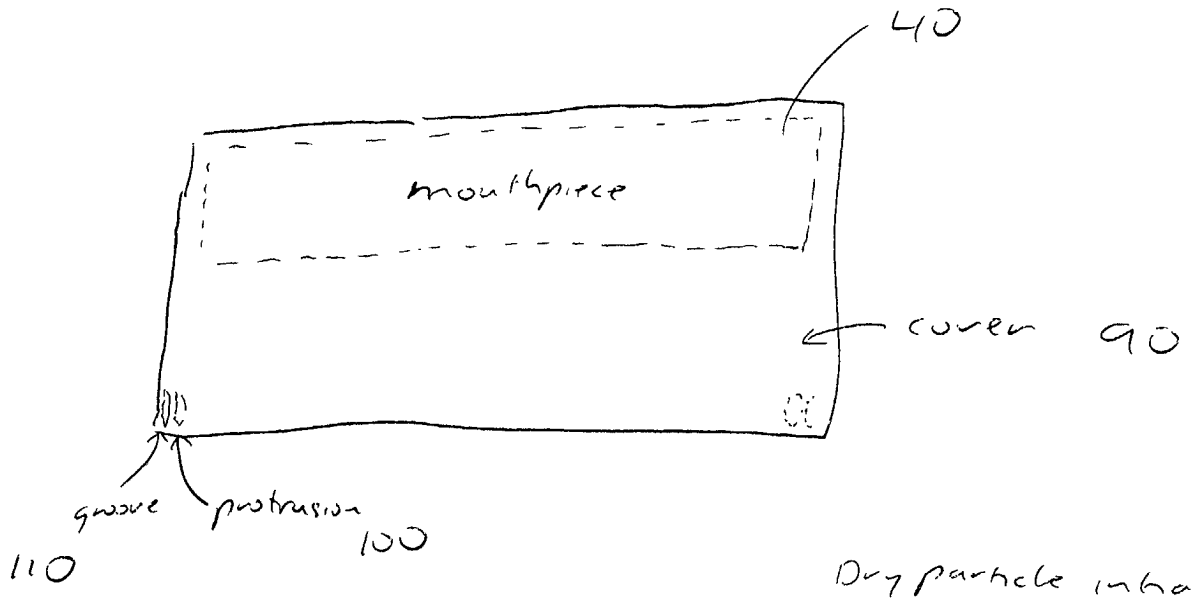
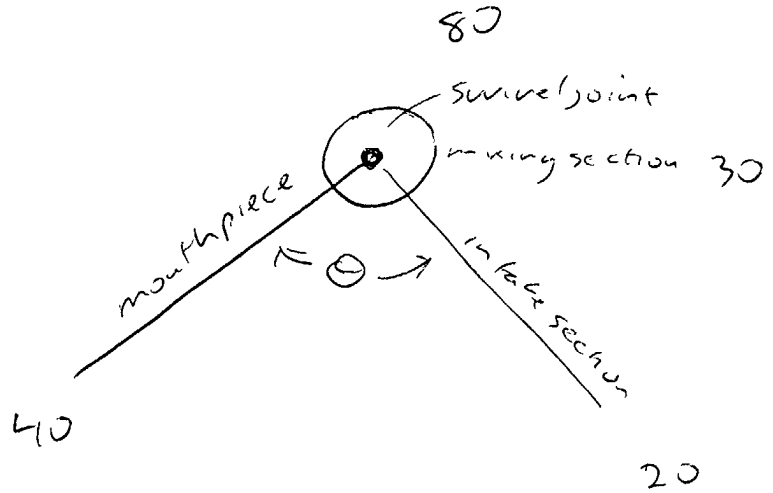


Figure 2


80
swivel joint
mixing section
30
mouthpiece
θ
inlet section
40
20

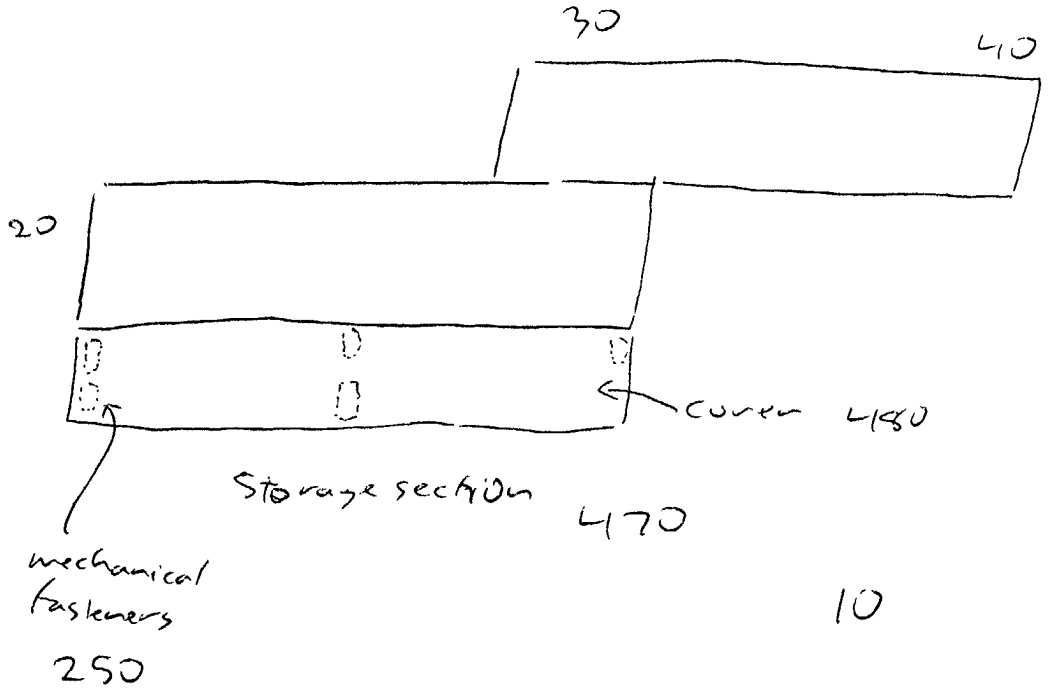
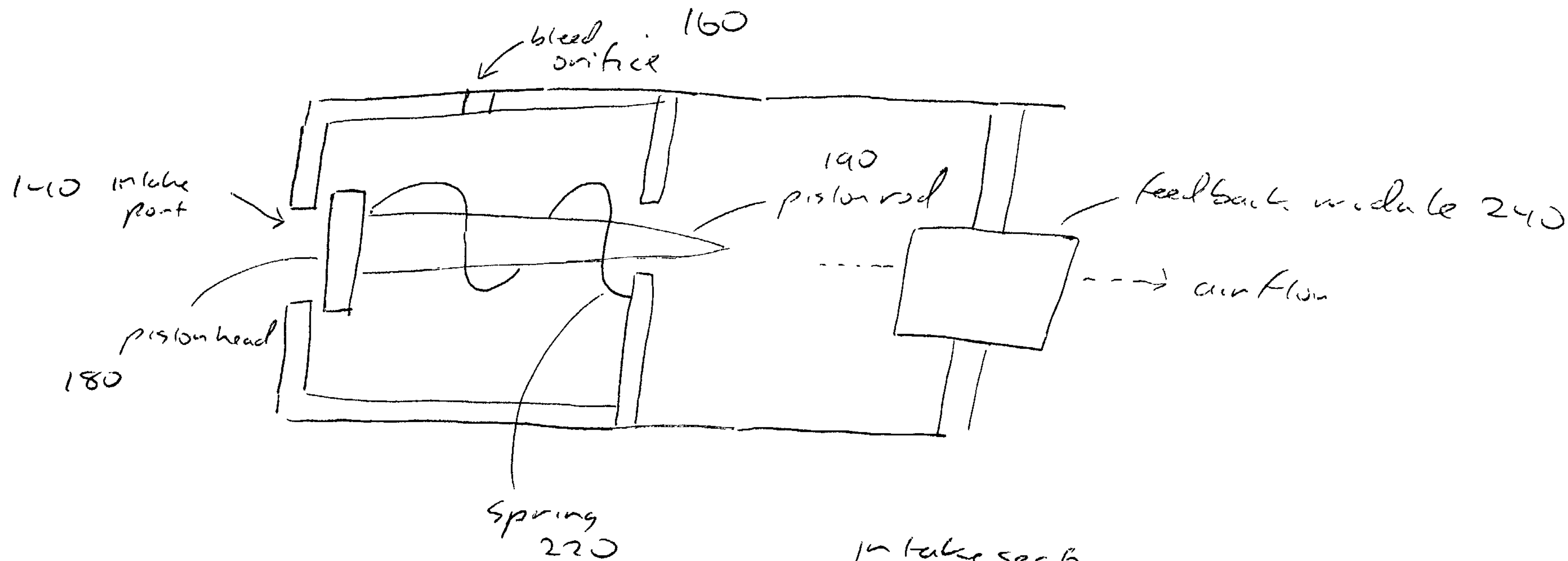


Figure 1 of 2 - 072106



piston normally closes intake port

2nd spring not shown

Figure 5

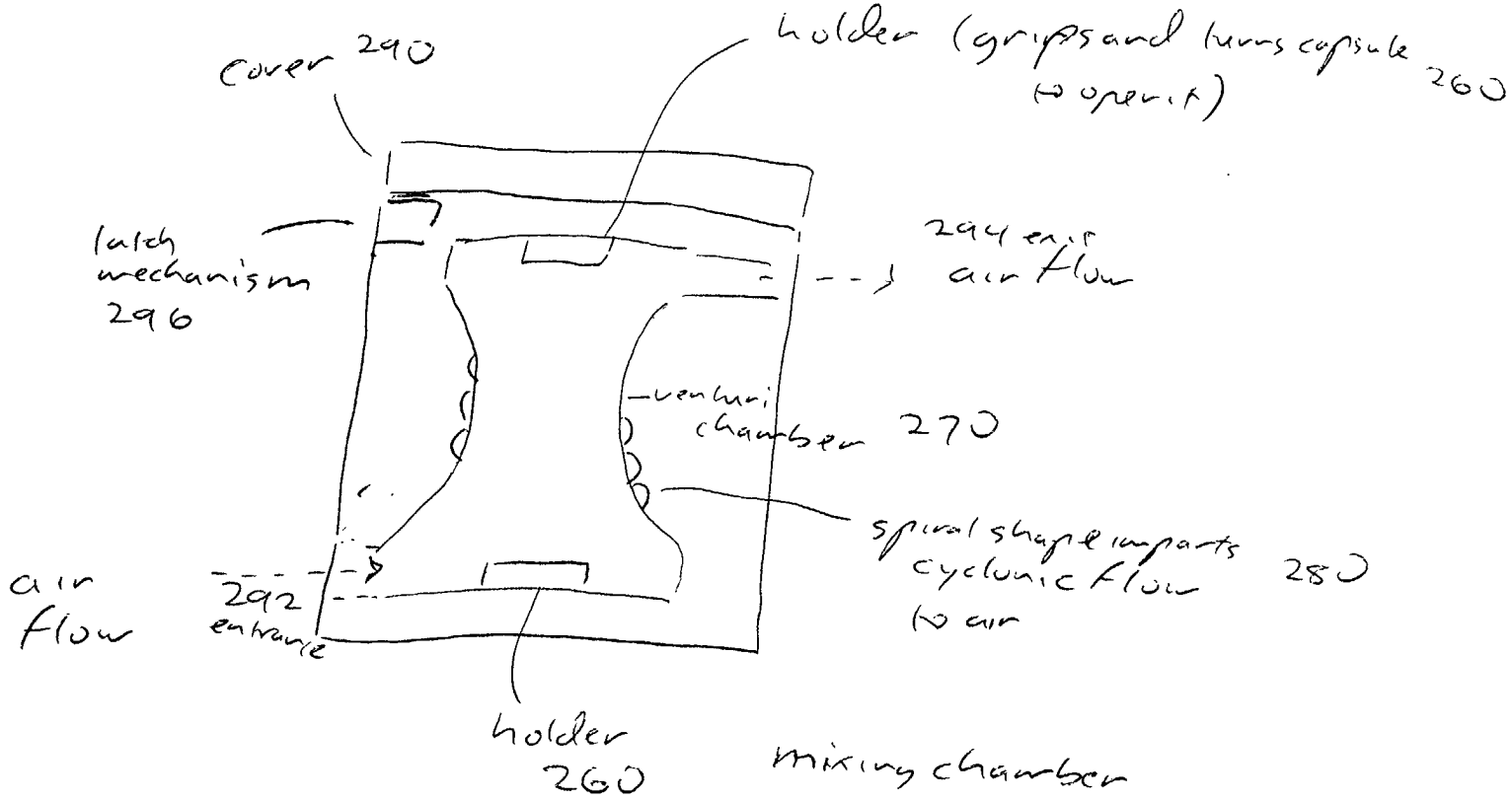
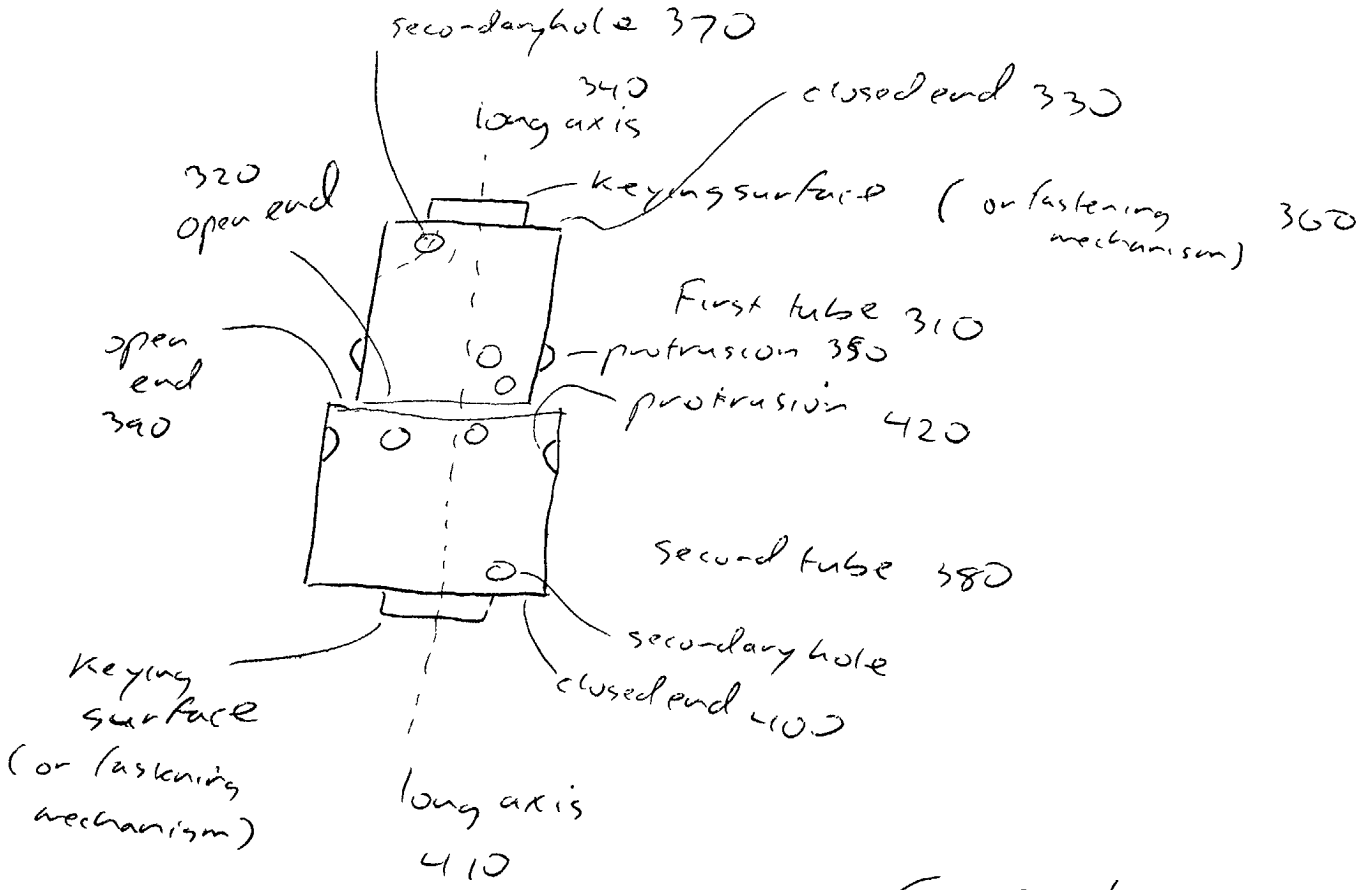


Figure 6



Capsule 300

Figure 7

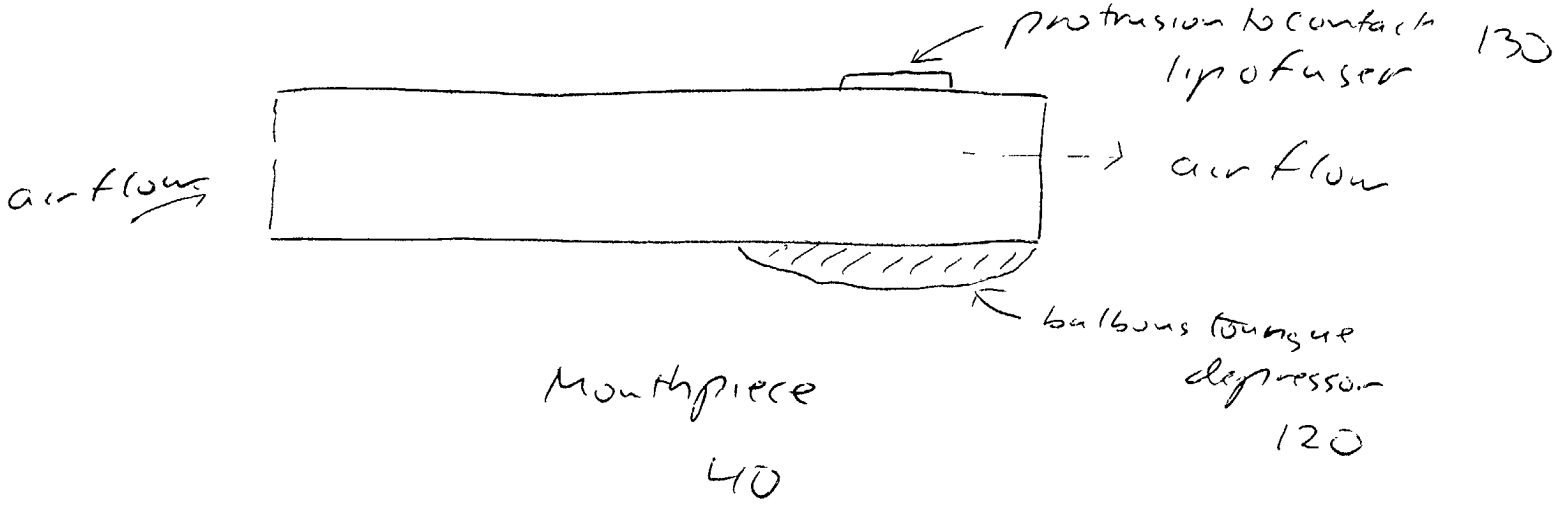

protrusion to contact lip of fuser
130
air flow
air flow
balbous tongue depression
120
Mouthpiece
40

Figure 8

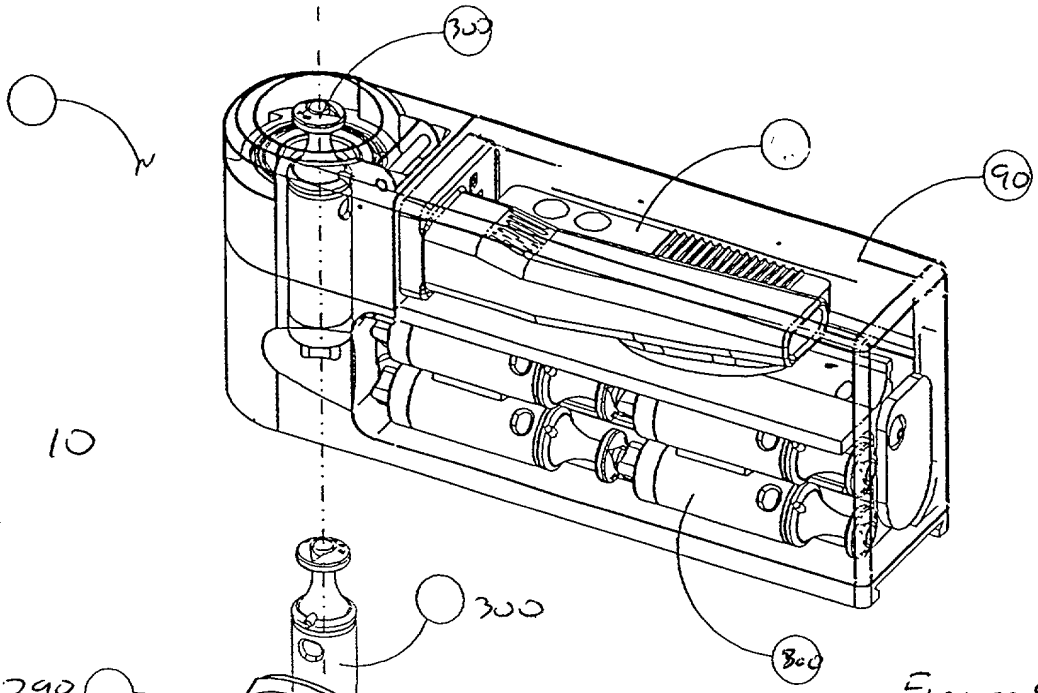


Figure 9

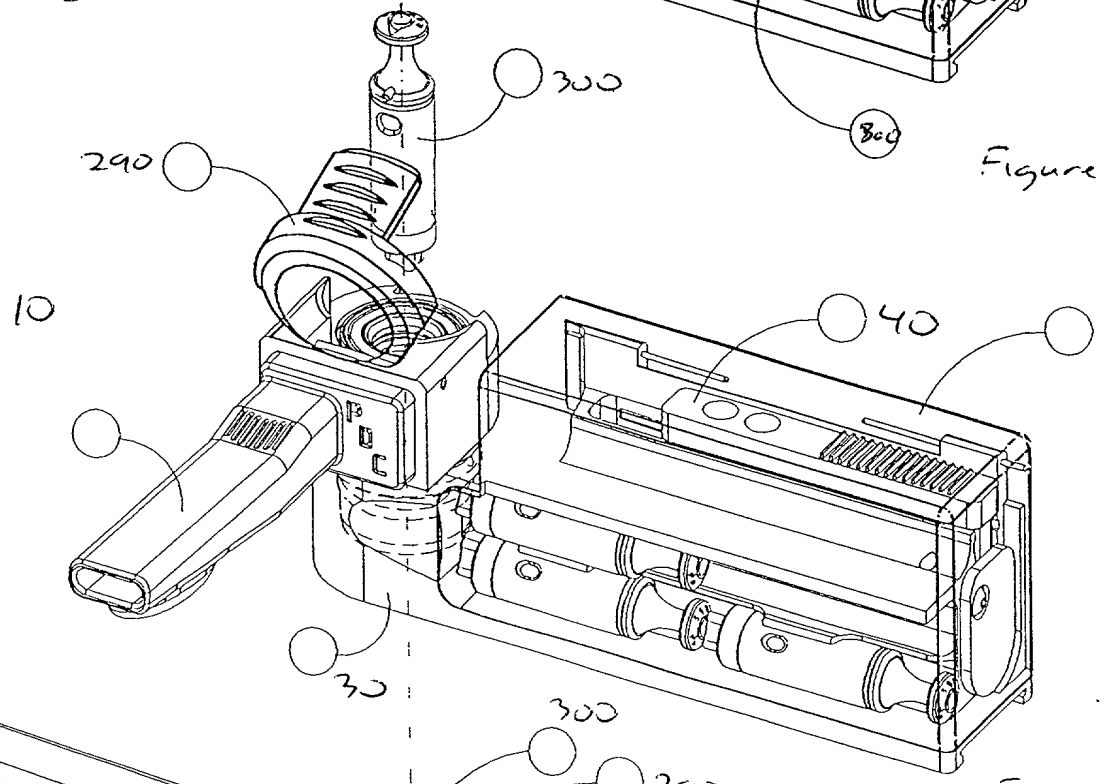


Figure 10

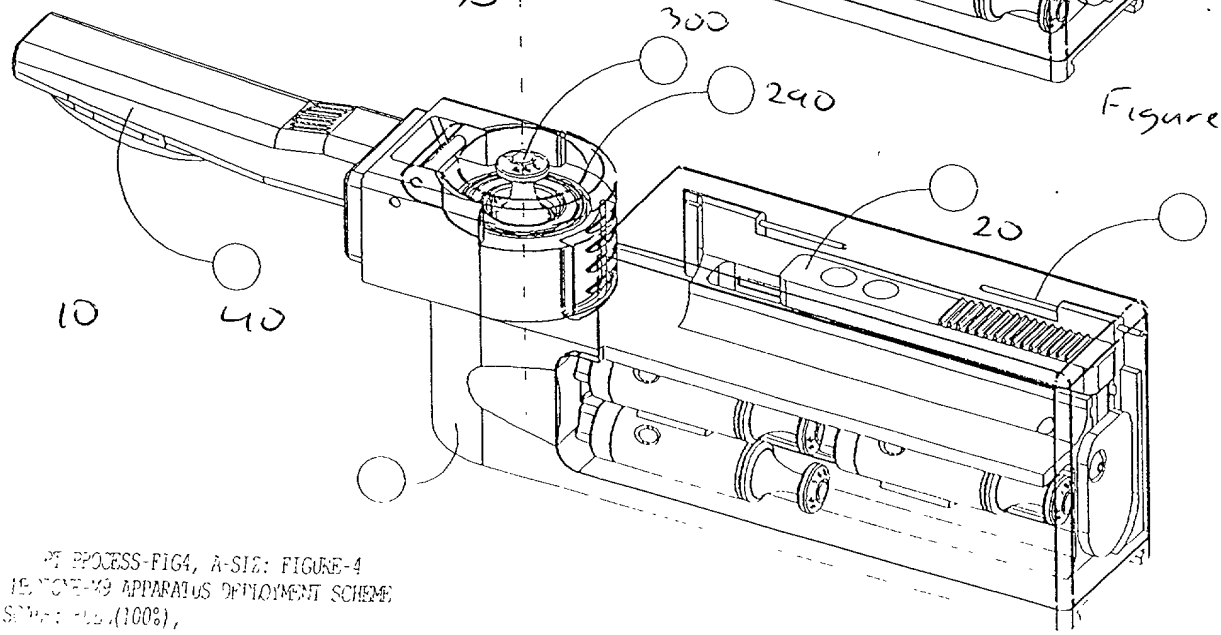


Figure 11

PT PROCESS-FIG4, A-SIZ: FIGURE-4
IS-TORE-99 APPARATUS DEPLOYMENT SCHEME
SCALE: NTS (100%),

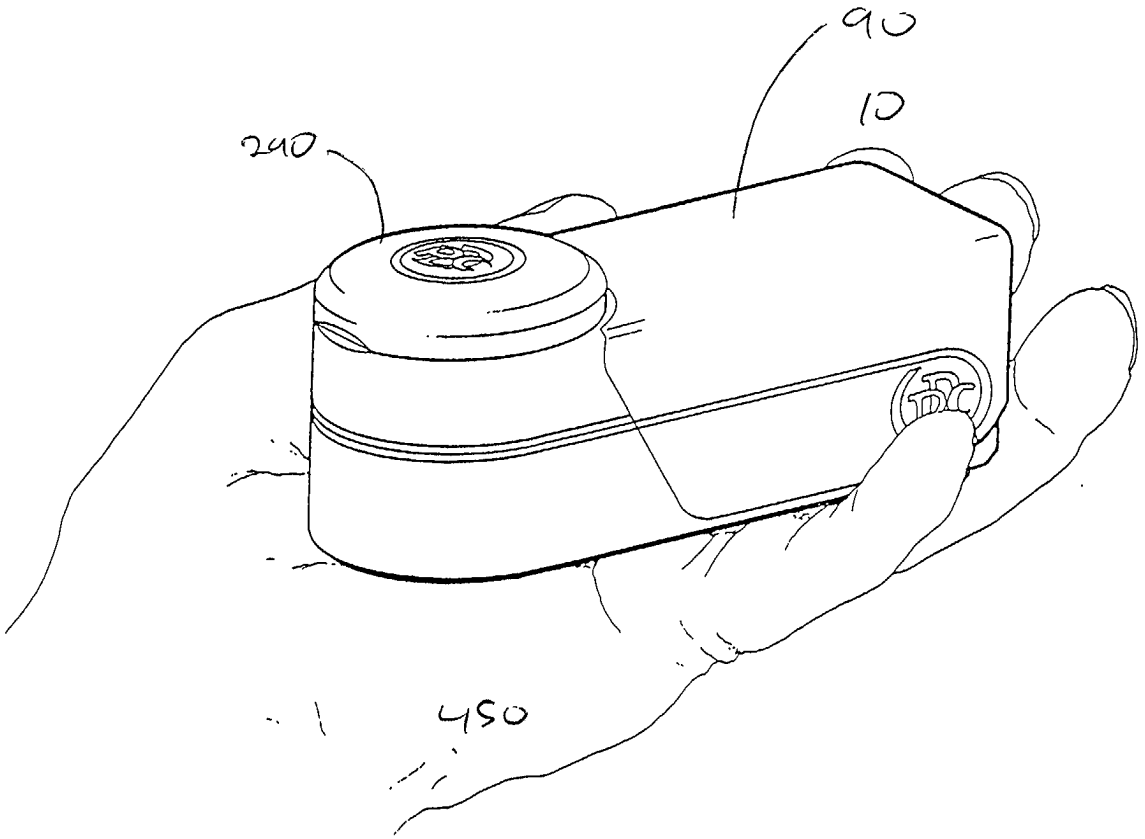


Fig 12

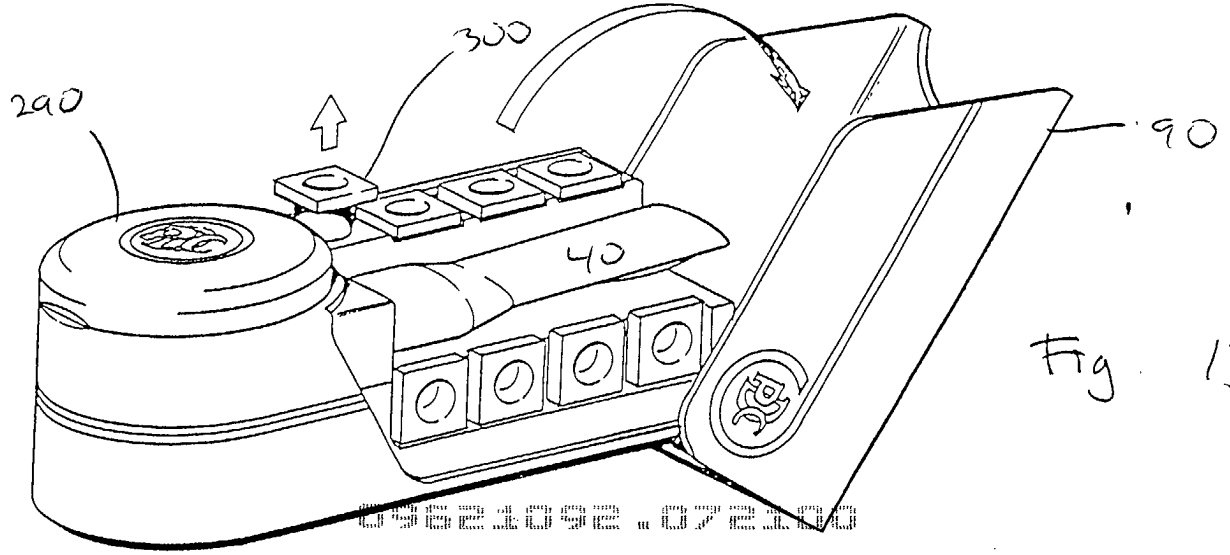
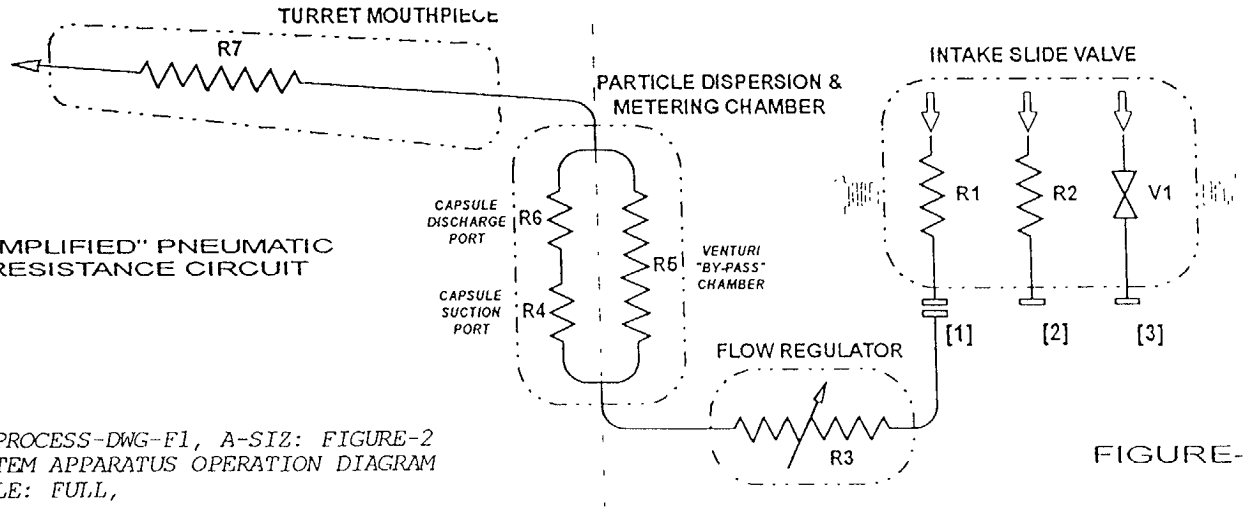


Fig 13

Fig. 15

Fig. 17



"SIMPLIFIED" PNEUMATIC
RESISTANCE CIRCUIT

PT-PROCESS-DWG-F1, A-SIZ: FIGURE-2
SYSTEM APPARATUS OPERATION DIAGRAM
SCALE: FULL,

FIGURE- 16

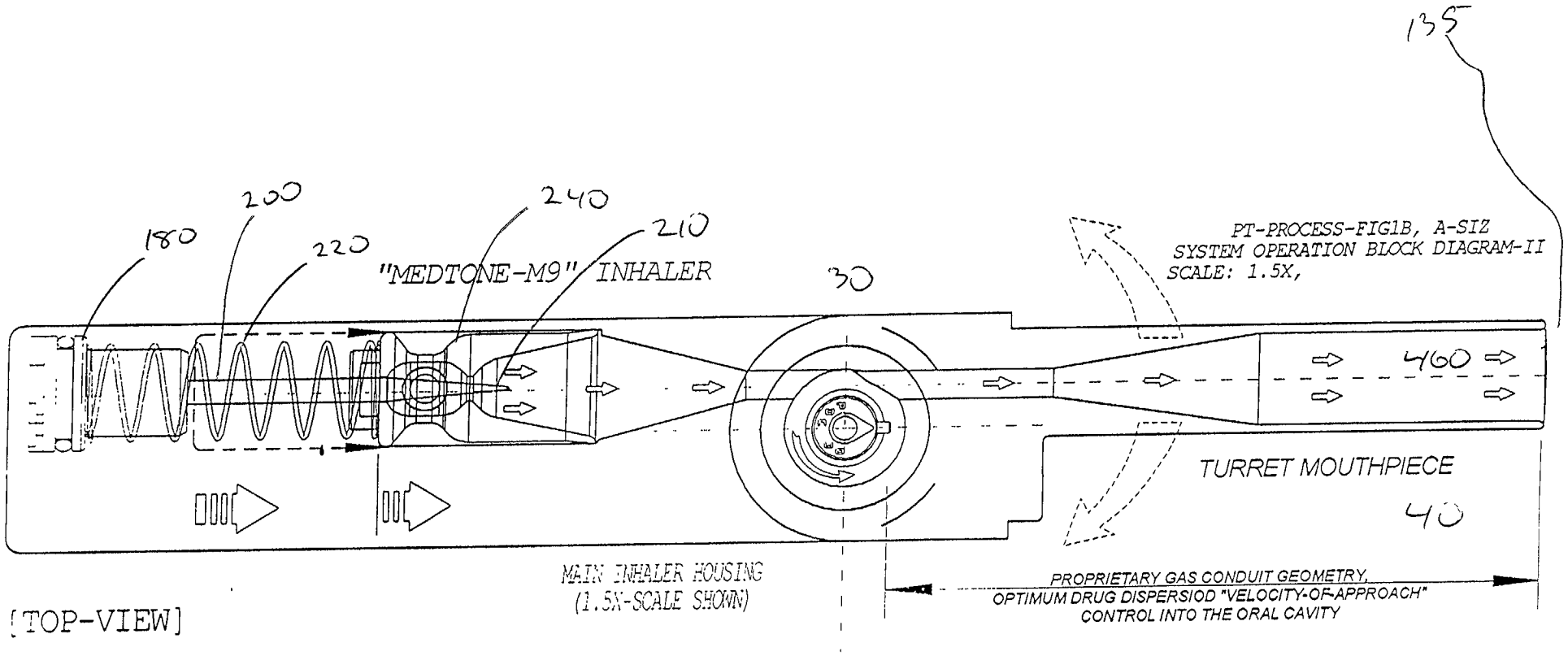

135
180
200
220
240
210
"MEDTONE-M9" INHALER
30
PT-PROCESS-FIG1B, A-SIZ
SYSTEM OPERATION BLOCK DIAGRAM-II
SCALE: 1.5X,
460
TURRET MOUTHPIECE
40
MAIN INHALER HOUSING
(1.5X-SCALE SHOWN)
PROPRIETARY GAS CONDUIT GEOMETRY,
OPTIMUM DRUG DISPERSIOD "VELOCITY-OF-APPROACH"
CONTROL INTO THE ORAL CAVITY
[TOP-VIEW]
20
10

Figure 17

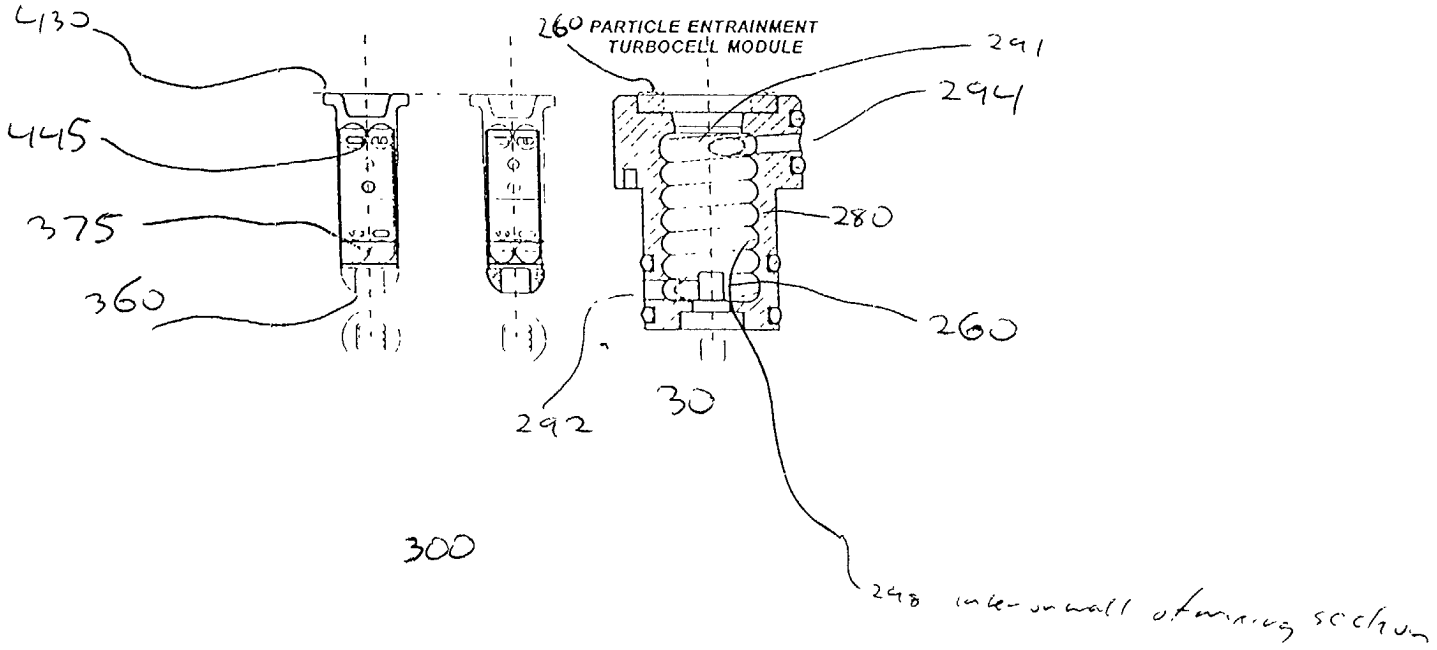

430
445
375
360
260 PARTICLE ENTRAINMENT TURBOCELL MODULE
291
294
280
260
292
30
300
248 inter-wall atomizing section

Figure 18

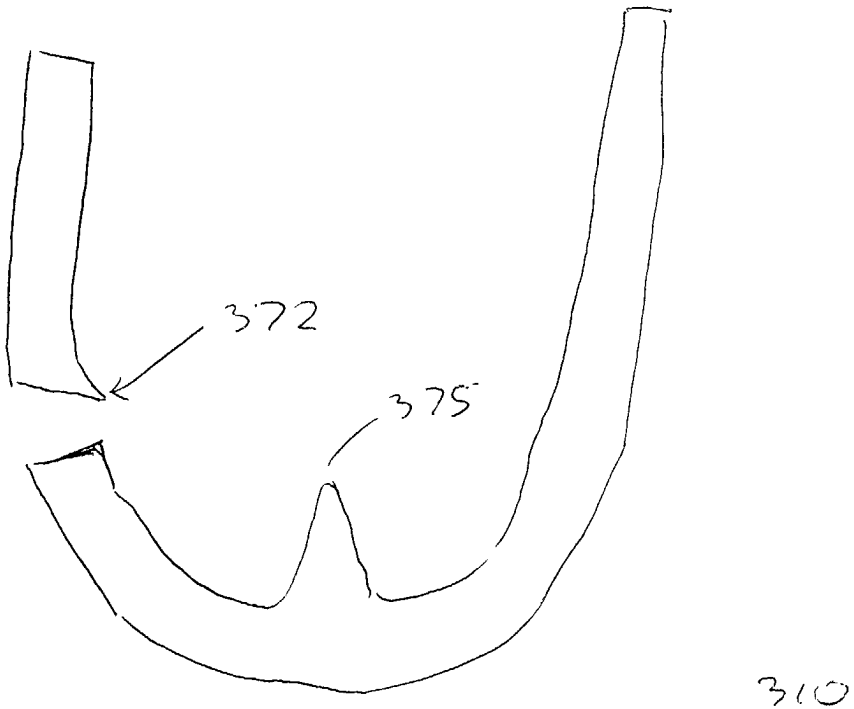


Figure 19

Please type a plus sign (+) inside this box → [+]

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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	PDC 116
First Named Inventor	Solomon S. Steiner
COMPLETE IF KNOWN	
Application Number	/
Filing Date	July 21, 2000
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

UNIT DOSE CAPSULES AND DRY POWER INHALER

(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below

Application Number(s)	Filing Date (MM/DD/YYYY)
60/145,464	July 23, 1999
60/206,123	May 22, 2000

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*
OR
☒ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Patrea L. Pabst	31,284	Felipe J. Farley	38,445
Robert A. Hodges	41,074	Zhaoyang Li	P-46,872
Kevin W. King	42,737		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

Name	Patrea L. Pabst, Esq.				
Address	Arnall Golden & Gregory, LLP				
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Country	United States	Telephone	(404)873-8794	Fax	(404)873-8795

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Solomon S.	Steiner

Inventor's Signature						Date	
Residence: City	Mount Kisco	State	NY	Country	US	Citizenship	US
Post Office Address	24 Old Wagon Road						
Post Office Address							
City	Mount Kisco	State	NY	ZIP	10507	Country	USA

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

PDC 116
20138/42

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 1

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Trent			Poole				
Inventor's Signature					Date		
Residence: City	South Amherst	State	MA	Country	USA	Citizenship	US
Post Office Address	59 Country Corners Road						
Post Office Address							
City	South Amherst	State	MA	ZIP	01002	Country	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Robert			Feldstein				
Inventor's Signature					Date		
Residence: City	Yonkers	State	NY	Country	USA	Citizenship	US
Post Office Address	1155 Warburton Avenue						
Post Office Address							
City	Yonkers	State	NY	ZIP	10701	Country	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Per B.			Fog				
Inventor's Signature					Date		
Residence: City	Bedford Hills	State	NY	Country	USA	Citizenship	US
Post Office Address	199 Green Lane						
Post Office Address							
City	Bedford Hills	State	NY	ZIP	10507	Country	USA

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.